



Clinical trial results:

Arthrose érosive des doigts : traitement par méthotrexate versus placebo- évaluation de l'action clinique et structurale (IRM dédiée)- Etude ADEM

Summary

| | |
|--------------------------|-----------------|
| EudraCT number | 2007-005437-11 |
| Trial protocol | FR |
| Global end of trial date | 15 October 2018 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 28 July 2022 |
| First version publication date | 28 July 2022 |

Trial information

Trial identification

| | |
|-----------------------|-----------|
| Sponsor protocol code | 06-API-07 |
|-----------------------|-----------|

Additional study identifiers

| | |
|------------------------------------|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | - |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | chu de nice |
| Sponsor organisation address | DRCI-Hôpital de Cimiez - 4 avenue reine victoria, Nice, France, 06003 |
| Public contact | Coordination Investigator , Pr Roux , +33 492039220, roux.c@chu-nice.fr |
| Scientific contact | Coordination Investigator , Pr Roux , +33 492039220, roux.c@chu-nice.fr |

Notes:

Paediatric regulatory details

| | |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|-----------------|
| Analysis stage | Final |
| Date of interim/final analysis | 15 October 2018 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 15 October 2018 |
| Global end of trial reached? | Yes |
| Global end of trial date | 15 October 2018 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

DEMONSTRATE THAT TREATMENT WITH METHOTREXATE IS MORE EFFICIENT ON PAIN THAT PLACEBO AFTER 3 MONTHS

Protection of trial subjects:

The patients signed an informed consent and were recruited into the Rheumatology Department of the CHU d e Nice

Background therapy: -

Evidence for comparator: -

| | |
|---|-------------|
| Actual start date of recruitment | 25 May 2010 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|------------|
| Country: Number of subjects enrolled | France: 64 |
| Worldwide total number of subjects | 64 |
| EEA total number of subjects | 64 |

Notes:

Subjects enrolled per age group

| | |
|---|----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 64 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

The patients are screening in the rheumatology.

Pre-assignment

Screening details:

The period is the inclusion period

Pre-assignment period milestones

| | |
|------------------------------|----|
| Number of subjects started | 64 |
| Number of subjects completed | 64 |

Period 1

| | |
|------------------------------|-----------------------------------|
| Period 1 title | Inclusion Period (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Monitor |

Arms

| | |
|--|---------------------------------|
| Arm title | Méthotrexate or placebo |
| Arm description: - | |
| Arm type | Experimental |
| Investigational medicinal product name | Methotrexate |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection/infusion |
| Routes of administration | Intramuscular use |

Dosage and administration details:

10 mg/week during 6 weeks

| Number of subjects in period 1 | Méthotrexate or placebo |
|--------------------------------|-------------------------|
| Started | 64 |
| Completed | 64 |

Baseline characteristics

End points

End points reporting groups

| | |
|--------------------------------|-------------------------|
| Reporting group title | Méthotrexate or placebo |
| Reporting group description: - | |

Primary: Pain measured by EVA at 3 months

| | |
|------------------------|---|
| End point title | Pain measured by EVA at 3 months ^[1] |
| End point description: | |

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:
at 3 months

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analyses is in the communication

| | | | | |
|-----------------------------|-------------------------|--|--|--|
| End point values | Méthotrexate or placebo | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 64 | | | |
| Units: EVA | 64 | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

At each visit

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 21.1 |
|--------------------|------|

Frequency threshold for reporting non-serious adverse events: 0 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: There are no non serious adverse events

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|-----------------------------|
| 12 November 2009 | Selection Criteria |
| 12 November 2009 | Add Questionnary |
| 04 February 2010 | Add evaluation adiponectine |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported